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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,434	07/03/2003	Aleksandar Milosavljevic	GMX 071394	4478

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10/02/2008

EXAMINER
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DEJONG, ERIC S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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10/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/613,434	<b>Applicant(s)</b> MILOSAVLJEVIC ET AL.	
	<b>Examiner</b> ERIC S. DEJONG	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 61-80 is/are pending in the application.
- 4a) Of the above claim(s) 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-73 and 75-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED OFFICE ACTION

Applicants response filed 06/19/2008 is acknowledged.

Claims 1-60 are canceled. Claims 61-80 are pending in the instant application. Claim 74 is withdrawn from prosecution (see the applicant's response filed 07/07/2006 and the Office action mailed 10/05/2006). Claims 61-73 and 75-80 are currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61-73 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (US Patent No. 5,841,975, see IDS filed 06/06/2005) in view of Burgoyne (US Patent No. 5,807,527).

The instant claims are drawn to methods of providing selective biological samples from a sample archive comprising providing an automated sample repository of a plurality of samples derived from biological sources, wherein said samples are stored on DNA immobilizing paper, providing an information database comprising medical history, clinical, or phenotypic information associated with said biological sources, determining a request from a sample selected from said plurality of samples, and removing at least a portion of said sample on DNA immobilizing paper based upon said request.

Layne et al. sets forth methods and apparatuses for sharing integrated testing services with a plurality of autonomous remote clients (see Layne et al., Abstract). Layne et al. teaches that the disclosed remote automated testing apparatus and method permit the submission and storage of biological test specimens (see Layne et al., Figure 4, col. 8, lines 21-51 and col. 10, lines 41-51), which reads on providing an automated

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sample repository comprising a plurality of sample derived from biological sources as known location within said repository as instantly claimed. Layne et al. further teaches that a process control tool performs a variety of annotation functions enabling researchers to deposit background information regarding biological specimens (see Layne et al., col. 10, line 21 through col. 11, line 4), which reads on providing an information database comprising medical history, clinical, or phenotypic information associated with said biological sources corresponding to said plurality of samples, and an integrated database accessible to a service provider and a remote requestor as instantly claimed. Layne et al. further teach the use of labels and identification codes affixed to samples (see Layne et al., col. 11, lines 2-4), which reads on supplying samples with unique identifiers, samples in a repository associated with optically readable identifiers, a catalog of said samples, detecting by optical image recognition means, identifying sample from information associated with sample in an information database, and ascertaining or detecting a location of an identified sample as instantly claimed. Layne et al. further teaches the use of standard laboratory modules (SLMs) and standard support modules (SSMs) for performing remote laboratory and analytical operations on samples, including retrieving specimens from storage, preparing specimens, and removing specimens, by user request (see Layne et al., col. 8, line 58 through col. 9, line 26), which reads on determining a request for a sample selected from said plurality and removing at least a portion of said sample and a mechanical means to separate at least a portion from other sample portions in a repository as instantly claimed. Layne et al. further teach the use of a process controller and task

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sequence controller which provides an interface between remote users and the automated test instrumentation (see Layne et al., Figures 5 and 6, col. 9, line 48 through col. 10, line 35, and col. 10, line 64 through col. 12, line 6), which reads on a request received by a service provider from a remote requestor, an associated database made available to a requestor via a computer network as instantly claimed. Layne et al. further teaches exemplary embodiments wherein samples comprise HIV virus and HIV-infected cells and protocols for performing ELISA assays (see Layne et al., Figure 10, col. 11, line 55 through col. 12, line 6, and col. 13, line 51 through col. 14, line 64), which reads on samples comprising a polynucleotide and analysis comprising contacting a sample portion with other matter to detect a specific binding event as instantly claimed. Layne et al. further teach examples wherein virus is generated and purified from infected cells (see Layne et al., col. 11, line 55 through col. 13, line 20) which reads on at least a portion of a sample is at least partially amplified as instantly claimed.

While Layne et al. sets forth the above described methods for sharing integrated testing services with a plurality of autonomous remote clients, Layne does not expressly teach the storage of samples derived from biological sources on DNA-immobilizing paper.

Burgoyne discloses a solid medium for use in the storage of DNA and DNA containing biological samples (e.g. blood) and methods involving the recovery or use of said DNA stored on a solid medium (See Burgoyne, Abstract and col. 1, lines 10-18). Burgoyne further discloses an exemplary embodiment wherein DNA is stored on cards

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made of absorbent paper (see Burgoyne, col. 4, lines 61 through col. 6, line 18), which reads on DNA-immobilizing paper as instantly claimed.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to use the solid DNA storage media, as taught by Burgoyne, as a substrate for storing biological samples, such as blood, for use in the methods for sharing integrated testing services with a plurality of autonomous remote clients, as taught by Layne et al., because Burgoyne et al. teaches that the disclosed solid media for storing DNA is inexpensive and resolves technical issues with storing and transporting DNA samples (see Burgoyne, col. 1, lines 33 through col. 2, line 14). One of ordinary skill in the art would further recognize that the combination of solid DNA storage media, as taught by Burgoyne et al., in combination with the method of integrated testing services, as taught by Layne et al., would yield predictable results.

### ***Response to Arguments***

Applicant's arguments filed 06/19/2008 have been fully considered but they are not persuasive.

In regard to the rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Layne et al. in view of Burgoyne, applicants argue that Layne et al. is not operable as an automated archive of selectable samples.

In response, contrary to applicants argument, Layne et al. expressly teaches the storage of samples until a time at which a portion of said sample is to be tested. Further,

in contrast to applicants argument, it is noted that no where in Layne et al. are samples destroyed after a portion of a sample is collected for subsequent analysis. Therefore it is maintained that it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to use the solid DNA storage media, as taught by Burgoyne, as a substrate for storing biological samples, such as blood, for use in the methods for sharing integrated testing services with a plurality of autonomous remote clients, as taught by Layne et al.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S DeJong/  
Primary Examiner, Art Unit 1631